

**PHARMACY PATIENT COUNSELING AMENDMENTS**

2012 GENERAL SESSION

STATE OF UTAH

**Chief Sponsor: Marie H. Poulson**

Senate Sponsor: \_\_\_\_\_

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**LONG TITLE****General Description:**

This bill amends the Pharmacy Practice Act.

**Highlighted Provisions:**

This bill:

- amends definitions;
- amends patient counseling provisions; ~~H~~→ [and]
- requires rulemaking; and ←~~H~~
- makes technical changes.

**Money Appropriated in this Bill:**

None

**Other Special Clauses:**

None

**Utah Code Sections Affected:****AMENDS:****58-17b-102**, as last amended by Laws of Utah 2010, Chapter 101~~H~~→ **58-17b-309**, as last amended by Laws of Utah 2011, Chapter 76 ←~~H~~**58-17b-613**, as enacted by Laws of Utah 2004, Chapter 280

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*Be it enacted by the Legislature of the state of Utah:*Section 1. Section **58-17b-102** is amended to read:**58-17b-102. Definitions.**

In addition to the definitions in Section 58-1-102, as used in this chapter:



(b) "Manufacturing" includes the preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, practitioners, or other persons.

(c) "Manufacturing" does not include the preparation or compounding of a drug by a pharmacist, pharmacy intern, or practitioner for that individual's own use or the preparation, compounding, packaging, labeling of a drug, or incident to research, teaching, or chemical analysis.

(36) "Medical order" means a lawful order of a practitioner which may include a prescription drug order.

(37) "Medication profile" or "profile" means a record system maintained as to drugs or devices prescribed for a pharmacy patient to enable a pharmacist or pharmacy intern to analyze the profile to provide pharmaceutical care.

(38) "Misbranded drug or device" means a drug or device considered misbranded under 21 U.S.C.S. Sec. 352 (2003).

(39) (a) "Nonprescription drug" means a drug which:

(i) may be sold without a prescription; and

(ii) is labeled for use by the consumer in accordance with federal law.

(b) "Nonprescription drug" includes homeopathic remedies.

(40) "Nonresident pharmacy" means a pharmacy located outside of Utah that sells to a person in Utah.

(41) "Nuclear pharmacy" means a pharmacy providing radio-pharmaceutical service.

(42) "Out-of-state mail service pharmacy" means a pharmaceutical facility located outside the state that is licensed and in good standing in another state, that:

(a) ships, mails, or delivers by any lawful means a dispensed legend drug to a patient in this state pursuant to a lawfully issued prescription;

(b) provides information to a patient in this state on drugs or devices which may include, but is not limited to, advice relating to therapeutic values, potential hazards, and uses; or

(c) counsels pharmacy patients residing in this state concerning adverse and therapeutic effects of drugs.

(43) "Patient counseling" means ~~[the]~~ written ~~[and]~~ or oral communication by ~~[the]~~ a pharmacist ~~↔~~ [or] , ~~↔~~ pharmacy intern ~~[of information, to the]~~ ~~↔~~ , or other person with dispensing authority ~~↔~~ with a patient ~~[or caregiver, in order], or~~

be dispensed only by prescription or is restricted to administration only by practitioners.

(64) "Retail pharmacy" means a pharmaceutical facility dispensing prescription drugs and devices to the general public.

(65) "Self-audit" means an internal evaluation of a pharmacy to determine compliance with this chapter.

(66) "Supervising pharmacist" means a pharmacist who is overseeing the operation of the pharmacy during a given day or shift.

(67) "Supportive personnel" means unlicensed individuals who:

(a) may assist a pharmacist, pharmacist preceptor, pharmacy intern, or licensed pharmacy technician in nonjudgmental duties not included in the definition of the practice of pharmacy, practice of a pharmacy intern, or practice of a licensed pharmacy technician, and as those duties may be further defined by division rule adopted in collaboration with the board; and

(b) are supervised by a pharmacist in accordance with rules adopted by the division in collaboration with the board.

(68) "Unlawful conduct" is as defined in Sections 58-1-501 and 58-17b-501.

(69) "Unprofessional conduct" is as defined in Sections 58-1-501 and 58-17b-502 and may be further defined by rule.

(70) "Veterinary pharmaceutical facility" means a pharmaceutical facility that dispenses drugs intended for use by animals or for sale to veterinarians for the administration for animals.

**Section 2. Section 58-17B-309 is amended to read:**

**58-17b-309. Exemptions from licensure.**

**(1) For purposes of this section:**

**(a) "Cosmetic drug":**

**(i) means a prescription drug that is:**

**(A) for the purpose of promoting attractiveness or altering the appearance of an individual; and**

**(B) listed as a cosmetic drug subject to the exemption under this section by the division by administrative rule; and**

**(ii) does not include a prescription drug that is:**

**(A) a controlled substance;**

**(B) compounded by the physician; or**

**(C) prescribed or used for the patient for the purpose of diagnosing, curing, mitigating, treating, or preventing a disease.**

**(b) "Injectable weight loss drug":**

**(i) means an injectable prescription drug:**

**(A) prescribed to promote weight loss; and**

358r ~~H~~→(B) listed as an injectable prescription drug subject to exemption under this section by the  
 358s division by administrative rule; and

358t (ii) does not include a prescription drug that is a controlled substance.

358u (c) "Patient counseling":

358v (i) is as defined in Section 58-17b-102; and

358w (ii) is limited to in-person face-to-face oral communication or communication by video  
 358x conferencing over a secure data connection.

358y [c] (d) "Prescribing practitioner" means an individual licensed under:

358z (i) Chapter 31b, Nurse Practice Act, as an advanced practice registered nurse with  
 358aa prescriptive practice;

358ab (ii) Chapter 67, Utah Medical Practice Act;

358ac (iii) Chapter 68, Utah Osteopathic Medical Practice Act; or

358ad (iv) Chapter 70a, Physician Assistant Act.

358ae (2) In addition to the exemptions from licensure in Section 58-1-307, the following individuals  
 358af may engage in the acts or practices described in this section without being licensed under this chapter:

358ag (a) a person selling or providing contact lenses in accordance with Section 58-16a-801;

358ah (b) an individual engaging in the practice of pharmacy technician under the direct personal  
 358ai supervision of a pharmacist while making satisfactory progress in an approved program as defined in  
 358aj division rule;

358ak (c) a prescribing practitioner who prescribes and dispenses a cosmetic drug or an injectable  
 358al weight loss drug to the prescribing practitioner's patient in accordance with Subsection (4); and

358am (d) an optometrist, as defined in Section 58-16a-102, acting within the optometrist's scope of  
 358an practice as defined in Section 58-16a-601, who prescribes and dispenses a cosmetic drug to the  
 358ao optometrist's patient in accordance with Subsection (4).

358ap (3) In accordance with Subsection 58-1-303(1)(a), an individual exempt under Subsection  
 358aq (2)(b) must take all examinations as required by division rule following completion of an approved  
 358ar curriculum of education, within the required time frame. This exemption expires immediately upon  
 358as notification of a failing score of an examination, and the individual may not continue working as a  
 358at pharmacy technician even under direct supervision.

358au (4) A prescribing practitioner or optometrist is exempt from licensing under the provisions of  
 358av this part if the prescribing practitioner or optometrist:

358aw (a) (i) writes a prescription for a drug the prescribing practitioner or optometrist has the  
 358ax authority to dispense under Subsection (4)(b); and

358ay (ii) informs the patient:

358az (A) that the prescription may be filled at a pharmacy or dispensed in the prescribing  
 358ba practitioner's or optometrist's office;

358bb (B) of the directions for appropriate use of the drug;

358bc (C) of potential side-effects to the use of the drug; and

358bd (D) how to contact the prescribing practitioner or optometrist if the patient has questions or  
 358be concerns regarding the drug; ←H

358bf            **Ĥ→ (b) dispenses a cosmetic drug or injectable weight loss drug only to the prescribing**  
 358bg **practitioner's patients or for an optometrist, dispenses a cosmetic drug only to the optometrist's**  
 358bh **patients; and**

358bi            **(c) follows labeling, record keeping, patient counseling, and storage requirements established**  
 358bj **by administrative rule adopted by the division in consultation with the boards listed in Subsection**  
 358bk **(5)(a).**

358bl            **(5) (a) The division, in consultation with the board under this chapter, the Physician Licensing**  
 358bm **Board, the Osteopathic Physician Licensing Board, the Physician Assistant Licensing Board, the Board**  
 358bn **of Nursing, and the Optometrist Licensing Board shall adopt administrative rules pursuant to Title**  
 358bo **63G, Chapter 3, Utah Administrative Rulemaking Act to designate:**

358bp            **(i) the prescription drugs that may be dispensed as a cosmetic drug or weight loss drug under**  
 358bq **this section; and**

358br            **(ii) the requirements under Subsection (4)(c).**

358bs            **(b) When making a determination under Subsection (1)(a), the division and boards listed in**  
 358bt **Subsection (5)(a), may consider any federal Food and Drug Administration indications or approval**  
 358bu **associated with a drug when adopting a rule to designate a prescription drug that may be dispensed**  
 358bv **under this section.**

358bw            **(c) The division may inspect the office of a prescribing practitioner or optometrist who is**  
 358bx **dispensing under the provisions of this section, in order to determine whether the prescribing**  
 358by **practitioner or optometrist is in compliance with the provisions of this section. If a prescribing**  
 358bz **practitioner or optometrist chooses to dispense under the provisions of this section, the prescribing**  
 358ca **practitioner or optometrist consents to the jurisdiction of the division to inspect the prescribing**  
 358cb **practitioner's or optometrist's office and determine if the provisions of this section are being met by**  
 358cc **the prescribing practitioner and optometrist.**

358cd            **(d) If a prescribing practitioner or optometrist violates a provision of this section, the**  
 358ce **prescribing practitioner or optometrist may be subject to discipline under:**

358cf            **(i) this chapter; and**

358cg            **(ii) (A) Chapter 16a, Utah Optometry Practice Act;**

358ch            **(B) Chapter 31b, Nurse Practice Act;**

358ci            **(C) Chapter 67, Utah Medical Practice Act;**

358cj            **(D) Chapter 68, Utah Osteopathic Medical Practice Act; or**

358ck            **(E) Chapter 70a, Physician Assistant Act.**

358cl            **(6) Except as provided in Subsection (2)(d), this section does not restrict or limit the scope of**  
 358cm **practice of an optometrist or optometric physician licensed under Chapter 16a, Utah Optometry**  
 358cn **Practice Act. ←Ĥ**

359            Section **Ĥ→ [2] 3 ←Ĥ** . Section **58-17b-613** is amended to read:

360            **58-17b-613. Patient counseling.**

361            **(1) [Every] A class A pharmacy [facility] shall [orally offer to counsel a patient or a**  
 362 **patient's agent in a personal] provide oral patient counseling by in-person face-to-face**

pharmacist at the dispensing pharmacy during normal business hours and receive oral counseling, with respect to each prescription drug dispensed if the patient provides or the prescription is otherwise provided to the pharmacy facility by a means other than personal delivery, and the dispensed prescription drug is mailed or otherwise delivered to the patient outside of the pharmacy facility.]

(2) A class D pharmacy shall provide oral patient counseling by telephone, or by video conferencing over a secure data connection, for each prescription drug it dispenses to a patient in this state.

(3) (a) [The provisions of Subsections (1) and (2) do not apply to] If a class A pharmacy or a class D pharmacy dispenses a prescription drug for a patient who is incarcerated [patients or persons] ~~H→~~ [or otherwise under the jurisdiction of] by ~~←H~~ the Utah Department of Corrections

or a county detention facility[. (b) A] in this state, the pharmacy shall provide patient counseling for the prescription by written ~~H→~~ or oral ~~←H~~ communication

[with a person described in

Subsection (3)(a) shall be used by a pharmacist or pharmacy intern] ~~H→~~ [in lieu of] ~~←H~~ [a face to face or

telephonic communication for the purpose of counseling the patient] ~~H→~~ [the oral communication

~~required under Subsection (1) or (2)] ←H .~~

~~H→~~ (4) This section shall be implemented in accordance with rules made by the division in consultation with the Board of pharmacy and in accordance with Title 63G, Chapter 3, Utah Administrative Rulemaking Act. ~~←H~~

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Legislative Review Note  
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Office of Legislative Research and General Counsel